

***In re National Prescription Opiate Litigation: MDL 2804***

**Defendants' CSA Compliance Brief – Summary Sheet**

Plaintiffs ask the Court to rule now, without a trial, that 16 Defendants violated the Controlled Substances Act (CSA). *See* Dkt. 1910 (Br.) at 1. Plaintiffs' motion is wrong on the law. It is also riddled with disputed facts that preclude summary judgment.

***First***, Plaintiffs' motion is based on the notion that the CSA imposes "duties" the Court can enforce, including a duty "to refrain from shipping orders flagged as 'suspicious' unless it has been determined that the order is not likely to be diverted." Br. at 1. As explained in Defendants' separate response to Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties under the CSA (Defs. CSA Duties Br.), no such duties exist under the CSA. Nor can DEA impose duties on registrants through informal guidance. But even assuming DEA's informal guidance is relevant, it cannot be applied retroactively. The record shows that Defendants modified their suspicious order monitoring (SOM) systems over time to come in line with DEA's changing expectations. At a minimum, the facts are disputed.

***Second***, Plaintiffs say Defendants failed to "maintain effective controls against diversion." Br. at 1. This, too, is hotly disputed. Among other things, there is no diversion in Cuyahoga and Summit Counties connected to Defendants. ***None***. Plaintiffs' SOM expert did not even "look at any particular order to see whether it was diverted." Rafalski Tr. 508:1-12 (Dkt. 1969-19/1983-16). "I don't have any direct knowledge of what happened to any of the drugs that were distributed to each of the pharmacies. I didn't conduct any analysis as of today that would give me that knowledge." *Id.* 582:9-19. All Plaintiffs have shown is that Defendants shipped opioids that filled legitimate prescriptions—in volumes approved by DEA to meet legitimate medical needs. Plaintiffs have come nowhere near meeting their burdens of proof and persuasion. With no evidence of diversion, Plaintiffs' motion must be denied.

***Third***, Plaintiffs seek to prove their claims through alleged CSA "violations," but the law forbids private enforcement of the CSA. Moreover, proof of such "violations" will not remove claims or Defendants from the case. It will not establish any element of any of Plaintiffs' state law claims. Nor will it satisfy Plaintiffs' burden under RICO to identify and prove the specific predicate acts committed by each Defendant that allegedly caused them harm. For these reasons, too, Plaintiffs' motion should be denied.

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